



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 18, 2013

Mr. Patrick Leong
Chief Operation Officer
Tekmedic (M) Sdn Bhd
Plot 4, Tanjung Kling Industrial Area
Tanjung Bruas Jetty, Tanjung Kling
Malacca, Malaysia 76400

Re: K121592

Trade/Device Name: Powder Free Blue Nitrile Examination Gloves Tested With
Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: December 20, 2012

Received: December 26, 2012

Dear Mr. Leong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Premarket Notification For Powder Free Blue Nitrile Examination Glove Tested With
Chemotherapy Drugs**

4.0 Indication For Use Statement

510 (K) Number (if known) : K121592

Device Name : **Powder Free Blue Nitrile Examination Glove Tested With
Chemotherapy Drugs**

Indication For Use :

A powder free nitrile examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

The tested chemotherapy drugs and their breakthrough detection time are as follows :

Chemotherapy Drugs & concentration	Average Breakthrough Detection Time
Carmustine (BCNU), 3300ppm	60.2
Cisplatin, 1000ppm	> 240 min
Cyclophosphamide (Cytoxan), 20,000 ppm	> 240 min
Dacarbazine (DTIC), 10,000 ppm	> 240 min
Doxorubicin Hydrochloride, 2000 ppm	> 240 min
Etoposide (Toposar), 20,000 ppm	> 240 min
Fluorouracil, 50,000 ppm	> 240 min
Ifosfamide, 50,000 ppm	> 240 min
Methotrexate, 25,000 ppm	> 240 min
Mitomycin C, 500 ppm	> 240 min
Mitoxantrone, 2000 ppm	> 240 min
Paclitaxel (Taxol), 6000 ppm	> 240 min
Thiothepa, 10,000 ppm	105.6
Vincristine Sulfate, 1000 ppm	> 240 min

Please note that the following drugs have low permeation times:

Carmustine – 60.2 minutes

Thiothepa – 105.6 minutes

Prescription Use _____
Part 21 CFR 801 Subpart D

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Elizabeth F. Claverie

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____